REMARKS

This Amendment is responsive to the Office Action mailed April 3, 2003. In that Office Action, the Examiner deemed the previous Restriction Requirement final and withdrew claims 17-29 and 34-36 from further consideration as being drawn to a nonelected invention. Additionally, the Examiner rejected claims 1-3, 9-13, 15, 16, and 30-33 under 35 U.S.C. §102(b) as being anticipated by Myers, U.S. Patent No. 5,716,397 ("Myers"). Claims 1-4, 7, 9-13, 15, 16, and 30-33 were rejected under 35 U.S.C. §102(b) as being anticipated by Wright et al., U.S. Patent No. 5,306,296 ("Wright"). Claims 5, 6, and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wright and further in view of Carpentier et al., U.S. Patent No. 5,061,277 ("Carpentier"). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Wright or Myers, and further in view of Loch et al., U.S. Patent No. 6,174,332 ("Loch").

With this Response, claims 1-3 and 10 have been amended, claims 17-29 and 34-36 have been cancelled, and claims 37-41 have been added. It is believed that all claims are now in a condition for allowance. Notice to that effect is respectfully requested.

Claim Rejections under 35 U.S.C. §§ 102(b) and 103(a)

The Examiner's rejection of claim 1 under 35 U.S.C. § 102(b) is respectfully traversed for at least the following reasons. Claim 1 recites to an annuloplasty band including a stiffening element disposed within a sheath. Additionally, each end of the stiffener includes an eyelet. Furthermore, amended claim 1 recites that the shape of the sheath conforms to the shape of the eyelets.

Myers fails to teach or suggest the limitations of amended claim 1. A fundamental teaching of Myers is that upon assembly, at least one of the eyelets is exposed outside of the sheath to aid in removal. (*See* Myers, FIGS. 3, 4, 7 and 6(a-g); C2:L21-27). In contrast, claim 1 requires that both eyelets be within the sheath. This requirement is derived via the limitations of the eyelets being disposed within the sheath and the sheath shape conforming to the eyelet shapes. A further distinction is Myer's failure to anticipate a sheath shape that conforms to an eyelet shape. The Examiner's attention is first directed to FIG. 5 of Myers. Stiffener **28** of FIG.

5 is shown with considerable space between it and the sheath. Additionally, none of the remaining figures show a sheath conforming to the eyelet shape. For example, the sheath **30** of FIG. 3 is uniform in shape. Finally, nowhere in Myers is a sheath conforming to an eyelet described.

Therefore, Myers does not teach or suggest the limitations of amended claim 1. In fact, Myers teaches away from those limitations. Myers seeks both insertion and removal of a stiffener. (*See* Myers, FIG. 4; C3:L34-46). Modifying Myers so that both eyelets are disposed within the sheath would defeat its functionality – the ability to remove the stiffener. Additionally, having a sheath conforming to the shape of the eyelets would interfere with one of Myer's stated criteria: "[The stiffener] must be removable with a minimum of stress...." (Myers, C3:L38-39). It would be counterintuitive to increase the stiffener's resistance to removal by having the sheath conform to the eyelet shape. Therefore, a requisite suggestion to modify Myers to meet the limitations of amended claim 1 does not exist.

Wright also does not teach claim 1 as amended. One embodiment of Wright may provide eyelets completely disposed within a sheath, but fails to teach a sheath shape conforming to the shape of the eyelets. In particular, FIG. 1 of Wright depicts a mitral valve ring 10 (C14:L17-22) embodiment including an internal flexible stiffening member 35. FIG. 2 depicts the internal structure of the mitral valve ring of FIG. 1 including the stiffener 35 disposed within a loose-fitting, folded tubular body or sheath 11 along with a series of drawstring windings 20, 21 and a radiopaque member 40. The stiffener 35 forms loops 36, 37. It is readily apparent that the sheath 11 shape fails to conform to the shape of the loops 36, 37 by comparing FIGS. 1 and 2. FIG. 6 of Wright supports such a lack of conformance by showing the stiffener **35** with considerable distance between it and the outer cloth layer (or sheath) **107**. None of the remaining figures show a sheath conforming to a stiffener eyelet shape and nowhere in Wright is a sheath conforming to an eyelet described. Nor does Wright suggest a sheath shape conforming to an eyelet's shape. Wright teaches that an expandable sheath is desirable. (*See* Wright, C4:L65-68 – C5:L1-3). In no way does an expandable sheath, increasing in width, suggest a sheath's conformance to eyelet shape. In fact, modifying Wright to provide a sheath conforming to a shape of the stiffener loop (or eyelet) would overtly impede tightening of the drawstrings 20,

why not?

21, the feature Wright was specifically designed to provide (Wright, column 4, lines 59-61). Thus, Wright teaches away from the invention of claim 1.

In light of the above, it is respectfully submitted that amended claim 1 is allowable over the cited references.

The Examiner proffered that claims 2 and 3 recited intended use limitations. It is respectfully submitted that claims 2 and 3 as amended denote structural limitations. The natural shape of either valve conveys an arcuate structure sufficiently definite to one of ordinary skill in the art. In addition to its dependency from claim 1, claim 3 is further distinguished over Wright as Wright's tricuspid valve ring embodiments do not include the use of a stiffener, let alone one with eyelets. (*See* Wright, FIGS. 7 and 8; C16:L26-62).

The Examiner's rejection of claim 10 under 35 U.S.C. § 102(b) is respectfully traversed. The limitations of amended claim 10 are not taught by Myers or Wright. The Examiner rejected claim 10, citing Myers as teaching "a sheath having position indicating markings." The markings disclosed in amended claim 10 refer to a sheath marked to indicate eyelet position – not merely "position indicating markings." As previously noted, Myers teaches exposed eyelets, whereas amended claim 10 recites a stiffening element "disposed not completely within the sheath." The exposed eyelets of Myers inherently fail to provide the limitation of marking a sheath to indicate eyelet position. An exposed eyelet need not and, in fact, cannot be marked on the sheath. Myers merely teaches demarcation of "core lumen" in order to avoid suturing the stiffener (Myers, C4:L16-20), whereas amended claim 10 contemplates marking eyelet position to ensure suturing. Additionally, Myers teaches away from marking the sheath to indicate eyelet position as one eyelet is always external to the sheath.

Wright also fails to teach marking eyelet position. The Examiner has not identified the particular elements of Wright that purportedly teach the "eyelet position marking" of amended claim 10. Wright's elements **208** and **209** are external loops used when there is no stiffener. (*See* Wright, FIG. 7, 8; C16:L40). Element **210** is explicitly referenced as a "colored marker," but it is located at the center of the posterior section of the annulus. (*See* Wright, C16:L44). Therefore, **210** does not mark eyelet position. References **31** and **32** are taught as "anchor points," not as eyelet position demarcations. (*See* Wright, C14:L50-55). They merely anchor the

stiffener and do not necessarily demarcate the eyelets. Finally, **33** and **34** are colored markers that serve to generally orient the device to the annulus; however, never are they designated as corresponding to the eyelets' positions. (*See* Wright, C14:L40-45). It is also relevant to note that there is no motivation for Wright to include markings designating the eyelet positions as the eyelets are used in conjunction with the internal drawstring mechanism serving to dilate the ring. A surgeon will never need to locate the eyelets associated with the Wright device during use; thus, internal eyelet position relative to the sheath is of no consequence. Once again, both Wright and Myers fail to teach the limitations of amended claim 10. In fact, both teach away from marking eyelet position on the sheath. Thus, claim 10 is allowable over the cited references.

Examiner rejected claim 16 as anticipated by both Wright and Myers. The Examiner cites FIG. 4 of Myers as teaching a general saddle shape in the z-direction. Neither FIG. 4 nor the text of Myers indicates a general saddle shape either explicitly or inherently. The two-dimensional rendering of FIG. 4 is ambiguous at best as to z-plane geometry and nowhere in the Myers text is a saddle shape taught. Wright, on the other hand, illustrates the entire ring as being moveable to a saddle shape in FIG. 4B. In particular, the anterior portion 13 (that otherwise includes the stiffener 35 (see FIG. 2)) can hinge relative to a remainder thereof; normally, however, the entire ring is planar (Wright, C18:L31-36). Importantly, Wright teaches that this alleged saddle shape is prompted in response to movement of the annulus following implant. In fact, Wright expressly states, "[t]he angle, if any, in which the framework [the flexible stiffener] lies is not a function of the annuloplasty ring per se but rather of configuration of the heart, or other organ, to which the ring is applied...." (*See* Wright, C18:L31-52). Therefore, Wright does not teach or suggest a saddle shaped stiffening element as expressly stated in claim 16. Instead, Wright merely describes a flexible stiffening element that may be temporarily hinged to take the general shape of a mitral valve annulus, but, as manufactured, is planar. The stiffener of Wright does not and cannot independently provide a saddle shape, as otherwise set forth in claim 16. Thus, not only does Wright fail to anticipate claim 16, it teaches away from a stiffener incorporating a saddle shape as a distinct structural limitation. Amended claim 16 is therefore distinguishable from the cited references aside from its dependency on claim 1.

The Examiner's rejection of claims 4-9 and 11-15 under 35 U.S.C. § 102(b) is respectfully traversed. Claims 4-9 and 12-15 are allowable as they depend from amended claim 1. Claim 11 depends from claim 10 and is allowable for the same reasons as claim 10. The Examiner's rejection of claims 5, 6, 8, and 14 under 35 U.S.C. § 103(a) is respectfully traversed as well. Claims 5, 6, 8, and 14 depend from amended claim 1, allowable for the reasons previously stated. Therefore claims 5, 6, 8, and 14 are also allowable.

Finally, the Examiner's rejection of claims 30-33 under 35 U.S.C. § 102(b) as anticipated by Wright and Myers is respectfully traversed. Myers discloses a stiffener thickness of "about 750 μm." (*See* Myers, C3:L47). Wright discloses a stiffener thickness of approximately .028 inches (*See* Wright, C14:L63-68) and a flexible member diameter of .020 inches (*See* Wright, C16:L57-59). These values in no way satisfy an overall band thickness of less than 3.0, 2.7, and 2.5 mm, as set forth in claims 30-32, respectively. Cross-sections of both Wright and Myers vividly illustrate that the asserted stiffener thickness does not equate to the overall band or ring thickness. (*See* Wright, FIG. 6; Myers, FIG. 5). In fact, Myers and Wright simply reflect previous ring or band designs that include stiffeners in which no concern is given to reducing overall thickness as much as possible (the failure to actively pursue such "low profile" designs resulting in thicknesses well in excess of 3mm). Therefore, Wright and Myers do not teach or suggest claim 30 and dependent claims 31-33. It is also of note that the surprising reduction of the potential for stenosis and turbulence within the valve, as well as onset of thrombus, argues that a low-profile limitation is non-obvious. (*See* Specification P22:L9-15).

In sum, Examiner's rejection of independent claims 1 and 10 (as amended) is respectfully traversed. In light of the above arguments, neither of the claims is anticipated or obvious in light of the prior art. As claims 2-9 and 11-16 depend from claim 1 their rejection is respectfully traversed. Examiner's rejection of independent claim 30 and claims 31-33 depending therefrom is respectfully traversed as well. Both Wright and Myers fail to teach or suggest overall band thickness or the motivation for such low profile bands and rings.

Newly Presented Claims

With this response, independent claim 37 and claims 38-41depending therefrom have been added. Newly presented claims 37-41 are believed to present patentably distinct subject matter sufficiently enabled by the Specification.

Allowable Subject Matter

In light of the above, Applicant believes independent claims 1, 10, 30, and 37 and claims 2-9, 11-16, 31-33, and 38-41 depending therefrom are in condition for allowance. Allowance of these claims is respectfully requested.

CONCLUSION

It is believed that all claims are now in a condition for allowance. Notice to that effect is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 500471.